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6713-Dr. W-Hf**REMARKS*****Amendment to the Claims***

Claims 1 and 2-8 are still pending. No amendments have been made.

Provisional Double Patenting Rejections

- (1) In a telephone conversation with the Examiner Jiang, it appears that U.S. Patent 6,620,420 was intended to be cited instead of U.S. Patent 6,503,894 (which is directed to an unrelated invention - "Pharmaceutical Composition and Method for Treating Hypogonadism"). A terminal disclaimer is concurrently filed with this application which should obviate the basis for this rejection.
- (2) The claims were also provisionally rejected as being obvious over U.S. Serial No. 10/602,392. A terminal disclaimer is concurrently filed with this application which should obviate the basis for this rejection.

(Note: An IDS has been submitted which incorporates the references cited in the '392 application)

35 U.S.C. 103(a) rejection

As no new prior art rejections were made, the applicants' position remains essentially unchanged from the position taken in the Appeal Brief. However, the applicants again would like to respectfully point out the errors in the Examiner's reasoning presented in her "Response to Argument" section.

First, the examiner refers to the "clear and convincing" language cited in *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA 1963) - emphasis added. Please note that this is a decision from the Custom Court of Patent Appeals (CCPA - precursor to the Federal Circuit) and "clear and convincing" is the proper standard at this level since the Examiner's decision has been upheld or taken as fact and as such is given great deference. However, this is NOT the situation before us. The U.S. PTO is an administrative agency and the MPEP clearly recites that the standard for determining patentability is "preponderance of evidence".

Second, MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." It is well known that "No *per se* rules of obviousness have been established by precedent, and reliance on any

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such rules that eliminate the need for fact-specific analysis of claims and prior art is legally incorrect and must cease, since use of *per se* rules in obviousness determination is inconsistent with 35 U.S.C. § 103, which entitles applicant to issuance of otherwise proper patent unless Patent and Trademark Office establishes that invention, as claimed in application, is obvious over cited prior art, based on specific comparison of that prior art with claim limitations." see *In re Ochial*, 37 U.S.P.Q. 1128, (Fed. Cir. 1995).

The applicants respectfully hold that the decisions cited by the Examiner are not sufficiently similar to the present set of facts:

(a) *In re Lohr* - In addition to the different evidentiary standard noted above, the decision in *Lohr* was directed toward a **compound not a composition**:

"When a new compound so closely related to a prior art compound as to be structurally obvious is sought to be patented based on the alleged greater effectiveness of the new compound for the same purpose as the old compound, clear and convincing evidence of substantially greater effectiveness is needed. Here there are no new properties, but merely an alleged improvement in the same property for use against the same pests." *Lohr*, 317 F.2d at 392, 137 USPQ 550-551.

(b) *In re McLaughlin* - *McLaughlin* dealt with a boxcar invention where the prior art essentially described the claimed invention save for a single element (i.e. there were a limited number of permutations which needed to be considered) which was addressed with a secondary reference and was well known to be used at the time the invention was made. This is not the case in the present application where stepping back to the time the invention was made and without benefit of the applicants' claims as a guideline, there would have been a virtually unlimited number of permutations which could have been made by the skilled artisan to the prior art.

The Examiner continues to argue about unexpected results and "optimization of parameters", but there has never been an assertion by the applicants that they are claiming unexpected results. Moreover, while presentation of unexpected results (evidence of secondary considerations) is certainly an option an applicant can pursue to try and address a holding of *prima facie* obviousness, there is no requirement to do so nor is there any requirement for unexpected results in order for a holding of patentability for the claims (see MPEP 2141 - *Graham v. John Deere* factors - If no evidence of secondary considerations are present, the Examiner simply evaluates obviousness on the first three factors).

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Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (5 pages) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 6 October 2004

By: Agata Glinska
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